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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/893,746 | 06/29/2001 | Ronald J. Pettis | 7767-173562 | 4733 |

7590 09/29/2004

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| EXAMINER | |
|---|---|
| HAYES, MICHAEL J | |
| **ART UNIT** | **PAPER NUMBER** |
| 3763 | |

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/893,746 | PETTIS ET AL. | |
| | Examiner | Art Unit | |
| | Michael J. Hayes | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 June 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-118* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-37, drawn to a method of delivering a substance into an intradermal space at a depth of 0.3-2mm, classified in class 604, subclass 506.

II. Claims 38-45, drawn to a microneedle, classified in class 604, subclass 264.

III. Claims 46-64, drawn to a method contacting a subject's skin with a device to deliver a bioactive substance to a dermal space, classified in class 604, subclass 500.

IV. Claims 65-74, drawn to a method of injecting a substance into the dermis to achieve improved systemic absorption relative to subcutaneous injection, classified in class 604, subclass 506.

V. Claims 75-96, drawn to a method of injecting growth hormone, heparin, or dopamine receptor agonist into the dermis to obtain systemic absorption, classified in class 604, subclass 507.

VI. Claims 97 and 98, drawn to an electroporation or thermal poration device, classified in class 604, subclass 20.

VII. Claims 99-118, drawn to a method of administering a substance to the dermis to achieve improved systemic absorption as compared to bolus subcutaneous administration, classified in class 604, subclass 506.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, IV, V, and VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions have separate utility such as methods not requiring the particular steps of the other inventions as discussed above. See MPEP § 806.05(d).

Inventions II and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions have separate utility such as devices not requiring the particular structure of the other invention as discussed above. See MPEP § 806.05(d).

Inventions I, III, IV, V, VII as compared to inventions II, VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device can be used in a method that does not access the intradermal space, such as delivering to a depth less than 0.3mm, or a device not achieving improved absorption compared to subcutaneous injection.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for inventions I, IV, and VII is not required for each of the inventions restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Several species to improved pharmacokinetics: species 1 drawn to increasing bioavailability, species 2 drawn to decreasing Tmax, species 3 drawn to increasing Cmax, species 4 drawn to decreasing Tlag, species 5 drawn to enhancing absorption rate. Species to administration time: species 6 drawn to less than 10 minutes, species 7 drawn to greater than 10 minutes. Species to substance administered: species 8 drawn to protein or peptide, species 9 drawn to a hormone, species 10 drawn to a nucleic acid, species 11 drawn to growth hormone, species 12 drawn to heparin, species 13 drawn to a dopamine receptor agonist, species 14 drawn to nanoparticles. Species to substance Mwt: species 15 drawn to less than 1000 daltons, species 16 drawn to greater than 1000 daltons. Species to device structure: species 17 drawn to a needle, species 18 draw to a microneedle array, species 19 drawn to three microneedles, species 20 drawn to six microneedles, Species to improved pharmacokinetics: species 21 drawn to improved ph as compared to after subcutaneous injection, species 22 drawn to improved ph as compared to when subcutaneous injecting, species 23 drawn to improved pharmacokinetics onset compared to subcutaneous injection. Species to administration method: species 24 drawn to bolus injection, species 25 drawn to repeated bolus injections, species 26 drawn to electroporation, species 27 drawn to thermal poration.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
27 September 2004

**MICHAEL J. HAYES**
**PRIMARY EXAMINER**